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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,391	11/12/2003	Randal Eckert	59157.8007.US02	5819
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PERKINS COIE LLP			ZEMAN, ROBERT A	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/706,391	ECKERT ET AL.	
	Examiner	Art Unit	
	Robert A. Zeman	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 29 May 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,2,4 and 6-54 is/are pending in the application.
- 4a) Of the above claim(s) 4,6-9,12,21-23,28-45 and 54 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2,10,11,13-20,24-27 and 46-53 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5-29-07</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed on 5-29-2007 is acknowledged. Claims 1, 13, 15, 24 and 26 have been amended. Claims 3 and 5 have been canceled. Claims 47-54 have been added. Claims 1-2, 4, 6-54 are pending.

Election/Restrictions

Newly submitted claim 54 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the elected invention was limited to compositions comprising a targeting moiety comprising SEQ ID NO:61.

Newly added claim 54 is drawn to a fusion peptide comprising SEQ ID NO:60

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 54 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Consequently, claims 4, 6-9, 12, 21-23, 28-46 and 54 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Claims 1-2, 10-11, 13-20, 24-27 and 47-53 are currently under examination.

Information Disclosure Statement

The Information Disclosure Statement filed on 5-29-2007 has been considered. An initialed copy is attached hereto.

Claim Objections

Claims 1-2, 24 and 47-53 are objected to as being drawn, in part, to non-elected inventions. Contrary to Applicant's assertion, the amendments to the instant claims are not sufficient to overcome the objection. Appropriate correction is required.

Claim Rejections Withdrawn

The provisional double patenting rejection of claims 1, 2 and 18 under 35 U.S.C. 101 as claiming the same invention as that of claims 1-3 of copending Application No. 10/077,624 is withdrawn in light of the amendment thereto.

The provisional double patenting rejection of claim 5 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 21 of copending Application No. 10/077,624 is withdrawn. Cancellation of said claim has rendered the rejection moot.

The rejection of claims 1-2, 5 18-20, 24-27 under 35 U.S.C. 102(e) as being anticipated by Shi et al. (U.S. Patent Application Publication US 2004/0052814A1) is withdrawn in light of applicant's arguments.

The rejection of claims 1-2, 5, 18-20 and 24-27 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Goldenberg (U.S. Patent 5,332,627) is withdrawn in light of the amendment thereto.

*Claim Rejections Maintained**35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 10-11, 13-20, 24-25 and 47-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for the reasons set forth in the previous Office action in the rejection of claims 1-3, 10-11, 14-20 and 24-27. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant argues:

1. Amended claim 1 is directed to a composition useful for specifically killing microbial organisms. The compositions comprises a targeting moiety and an antimicrobial moiety wherein the targeting moiety is fused in-frame with the anti-microbial peptide moiety and wherein the targeting moiety specifically recognizes a target microbial organism and wherein said composition has an anti-microbial effect on said organism.
2. One aspect of the invention is that the composition has an antimicrobial effect on a target microbial organism and that the targeting moiety is fused in-frame with the anti-microbial moiety.
3. The prior art references disclose antibody conjugates that include a therapeutic agent chemically coupled to a targeting component. The drawback being the non-specific linkages of said agents to unknown sites on the antibody molecule.
4. The level of one ordinary skill in the art is a graduate level scientist in biology and there was a high level of skill in the art at the time the instant application was filed.

5. The art provides a number of examples of predictability.
6. The application provides ample examples and direction for experimentation.
7. The instant application provides a number of examples for the targeting moiety and the anti-microbial moiety.
8. The specification discloses step-by-step methods to generate species-specific targeting moieties, make the claimed composition and determine the properties of the composition.

All the methods needed to practice the invention are known in the art.

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Points 1 and 2, the instant claims require that the claimed composition "specifically kills" the target organisms. The specification fails to disclose methods of identifying targeting moieties that bind **only** to one specific organism (i.e. said binding moiety cannot bind to any other microbial organism).

With regard to Points 3 and 5, the art is silent with regard to targeting moieties that can only bind to a single microbial organism. Moreover, there is no way to predict whether a given binding moiety is specific for only one microbial organism.

With regard to Points 6 and 7, none of the examples in the specification disclose a targeting moiety that can only bind to a single microbial organism.

With regard to Point 8, the targeting moieties of the instant invention need to be able to bind to only one organism not merely be species specific.

As outlined previously, the aforementioned claims are drawn to compositions useful for the treatment of microbial organisms wherein the targeting moieties of said compositions could only bind to a single microbial organism.. The specification

however, is silent on how such a composition would be used and equally silent on the efficacy of said compositions. People of skill in the art require evidence that a benefit can be derived by the application of a given substance. The specification, as filed, does not set forth that the claimed compositions provide any sort of therapeutic effect in any model system that can be applied (or extrapolated) to humans or higher mammals (or in humans themselves). The specification describes (prophetically, in most instances) how a given composition can be made but is silent on its therapeutic use. While the skill in the art of immunology is high, to date, prediction of a therapeutic benefit (effect) for any given composition is quite unpredictable. Moreover, while one may know how to make the composition, no evidence has been provided that illustrates or even suggest that the claimed pharmaceutical compositions are capable of eliciting a beneficial response, one of skill in the art has not been taught to use the claimed composition as a pharmaceutical, as is required by the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 24 and 47-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons set forth in the previous Office action in the rejection of claims 3, 24 and 26. Contrary to Applicant's assertion, the amendments to the instant claims are not sufficient to overcome the rejection.

As outlined previously, said claims recite language drawn to non-elected inventions making it impossible to determine the metes and bounds of the claimed inventions.

New Grounds of Rejection

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 24-27 and 49-53 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant has amended claim 1 to recite “wherein the targeting moiety is fused in-frame with the anti-microbial peptide...”. This phrase only appears in the specification, or original claims as filed with regard to the targeting moiety being a peptide (see paragraph [0012]) and as such does not provide support for the full breadth of the rejected claims. Therefore this limitation is new matter.

Claims 1-2, 10-11, 13-20, 24-27 and 47-53 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in

such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant has amended claim 1 to recite “specifically killing microbial organisms ...”. This phrase only appears in the specification, or original claims as filed with regard to the fusion protein G10Cato (see paragraph [0161]) and as such does not provide support for the full breadth of the rejected claims. Therefore this limitation is new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 10-11, 13-20, 24-27 and 47-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite by the use of the phrase “specifically killing microbial organisms”. It is unclear how one can “specifically kill” a plurality of species.

Claim 24 is rendered vague and indefinite by the use of the phrase “wherein the target microbial organism is *Pseudomonas*”. It is unclear how a genus of bacteria can constitute a single target organism.

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1-2, 10-11, 13-20, 24-27 and 47-53 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Goldenberg (U.S. Patent 5,332,627).

Goldenberg discloses the use of immunoconjugates to treat microbial infections wherein said immunoconjugate comprises an antibody or antibody fragment coupled to a therapeutic agent (see column 2, lines 37-57). Goldenberg further discloses that antimicrobial agents can be used to treatment of bacterial infections (see column 3, lines 7-17) and that the term "microbe" encompasses bacteria (see column 3, line 24). Additionally, Goldenberg discloses the use of antibody conjugates allows the localization

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of the therapeutic agent at the target site (i.e. the site of infection) with a higher efficiency and an enhanced target to non-target ratio (see column 3, lines 55-58). This would reduce the amount of antimicrobial agent required to treat a given infection and thereby reducing any toxicity associated with said agent. Finally, Goldberg et al. disclose that "any antibiotic or cytotoxic drug can be conjugated to the anti-pathogen antibody" (see column 16, lines 9-10). Since the term toxin reads on polypeptides and no size limit is associated with the claimed limitation "peptide" it is deemed the disclosure of toxins by Goldstein meets the limitation that the antimicrobial moiety be a peptide.

Goldenberg et al. differs from the instant invention in that they don't explicitly disclose that the targeting moiety and the anti-microbial moiety are "in-frame". However, given that the targeting moieties disclosed by Goldenberg et al. are peptides and they disclose toxin as antimicrobial moieties (which are also peptides) it would have been obvious for one of skill in the art to produce the said fusion protein recombinantly in order to take advantage of the increased ease and reproducibility associated with recombinant techniques. Moreover, since the term toxin is deemed to meet the limitation that the antimicrobial moiety can be a peptide, the specific anti-microbial moieties recited in claims 19, 20, 25 and 27 constitute obvious variations of the disclosed immunoconjugates.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not

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identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 2 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12 and 13 of copending Application No. 10/077,624. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim sets are drawn to compositions comprising targeting and antimicrobial moieties that are peptides. Moreover, as the compositions of the copending application are drawn to fusion proteins they two recited moieties are necessarily “in-frame”.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



ROBERT A. ZEMAN
PRIMARY EXAMINER

August 20, 2007